

Reconsideration and withdrawal of each of these rejections is requested based upon the following considerations.

Rejection Under 35 USC § 102(b)

The Cardinal reference (US 4,601,893) discloses a device with a multi-layer laminate comprising two or more core sheets containing an active agent for controlled release of two or more active agents (Col. 3, lines 15-36; Col. 5, line 53 to Col. 6, line 10). These core sheets are interposed or sandwiched between coextensive inert polymeric films (Col. 3, lines 26-32). Each core sheet can be, but need not be, separated by a coextensive inert polymeric film (Col. 6, lines 11-22). The three layer (sandwich) laminate comprising a single core sheet and two outer films can be rolled into a constrained cylindrical shape for oral administration (Col. 11, line 55 to Col. 12, line 66; Figure 3).

From the teaching discussed above, the device of Cardinal necessitates having a coextensive inert polymeric film as the outmost layer thereof. Cardinal does not teach or suggest that such a coextensive inert polymeric film contains a water-soluble drug dispersed in a carrier. On the other hand, Claim 1 of the present application defines "an outer layer" to contain a water-soluble drug dispersed in a carrier. Therefore, the preparations defined in Claim 1 and Claims 2,3,6 and 8 depending thereon are not

identical to the device of Cardinal in that the outermost layer contains a water-soluble drug.

Concerning the rejection under 35 USC § 102(b), the Examiner remarks that the device of Cardinal is comprised of two or more core sheets for controlled release of two or more active agents. The Examiner might (a) regard that "an outer layer" and "one or more inner layer(s)" in Claim 1, are equivalent to one of "two or more core sheets" and the other of "two or more core sheets" of the device of Cardinal, respectively, and (b) conceive that the claimed preparation may further comprise a coextensive inert polymeric film outside "an outer layer", since Claim 1 defines the preparation using the transitional phrase "comprising". However, according to such an interpretation of Claim 1, it is apparent that such a coextensive inert polymeric film should serve in turn as "an outer layer" when it is located outside the layer, which was "an outer layer" till then, and therefore, the "coextensive inert polymeric film" has to contain a water-soluble drug in such a case.

Cardinal actually teaches a device with a multi-layer laminate comprising two or more core sheets containing a drug. However, such a device is formed by rolling a multi-layer laminate into a constrained cylindrical shape (Col. 11, lines 66-68). On the other hand, in the present invention, each layer of the preparation is separately or simultaneously prepared in a mold to form a rod-like shape (page 12, line 8 to page 13, line 5). The device as shown in

Fig. 4 of the Cardinal reference is not a rod-like shaped device, but a ring-shaped device (Col. 5, lines 10-13). The device as shown in Fig. 3 of Cardinal may be rod-like in shape as pointed out by the Examiner, however, such a device comprises each layer located vorticosely in the diametrical direction of the device. In contrast, as shown in Fig. 1 and defined in Claim 1 of the present application, the preparation of the invention is a rod-like shape preparation comprising the outer and inner layers concentrically located in the diametrical direction of the preparation. Thus, the rod-like preparation defined in Claim 1 and Claims 2,3,6 and 8 depending thereon is quite different from the device of Cardinal in the manner of forming into a shape of a rod and a resulting configuration of the drug-containing layers concentrically in the diametrical direction.

Rejection Under 35 USC § 103

The Examiner has rejected claims 4, 5 and 7, assuming that the difference between the inventions of these claims and that of Cardinal would be obvious to a person skilled in the art. That is, the Examiner regards that incorporation of two or more active agents into a single layer and incorporation of the same active agent into different layers at different concentrations are obvious to a person skilled in the art.

The invention of Cardinal is directed to a laminate device with multiple layers (Col. 1, lines 18-20). As discussed above, Cardinal teaches that a laminate with multiple layers is rolled to form a constrained cylindrical device (Col. 11, lines 66-68). However, such rolling of the laminate inevitably results in multiple layers located vorticosely in the diametrical direction of the device. On the other hand, the rod-like preparation of the invention, as defined in Claim 1, comprises the outer and inner layers located concentrically in the diametrical direction. Thus, the preparation of the invention could not be obtained so long as a person skilled in the art follows the teaching of Cardinal, regardless of whether or not incorporation of two or more active agents into a single layer or incorporation of the same active agent into different layers at different concentrations would be obvious.

Claims 4, 5 and 7 depending on Claim 1, define a rod-like preparation as comprising each layer located concentrically. Therefore, the inventions of these claims are not obvious over Cardinal.

Furthermore, as discussed above, the outmost layer of the device of Cardinal is a coextensive inert polymeric film. For the coextensive inert polymeric film, Cardinal teaches that it should be "inert", "substantially impermeable to the use environment" and "substantially impermeable to an active agent" (Col. 5, lines 37-

42). From these teachings, a person skilled in the art would not be motivated to incorporate an active agent into a coextensive inert polymeric film, because it is anticipated that the active agent, when dispersed in the coextensive inert polymeric film, the addition of the agent would adversely affect the desired property of the film (for example, the "inert" property might be affected by an addition of an active agent, or the "substantially impermeable" property might be affected by channel formation in the film that is resulted from the release of the active agent, as described on page 2, lines 5-16 of the present specification). Therefore, a person skilled in the art is taught away from adding an active agent to the inert polymeric film, by the description of the film in Cardinal, as explained above. On the contrary, the outmost layer of the preparation of the invention, i.e., "an outer layer" in claim 1, must contain a water-soluble drug dispersed in a carrier. Therefore, the invention of Claim 1 is not obvious over Cardinal, and the inventions of claims 4, 5 and 7, depending thereon are not obvious accordingly.

#### CONCLUSION

Based upon the above remarks, and the arguments set forth therein, Applicants respectfully request that the Examiner now issue a Notice of Allowance clearly indicating that each of

Applicants' pending claims 1-8 are allowed and patentable under the provisions of Title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact John W. Bailey (Reg. No. 32,881) at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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0020-4771P